

DOCKETS MANAGEMENT BRANCH (hfa-305)
FDA -Docket No. 98N -1265
Food & Drug Administration
5600 Fishers Lane
Rockville, Md. 20857

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4 4 4 4 '99 MAY 19 P 4 :36

ATTN: DIRECTOR, FDA

Dear Sir or Madam,

I oppose the Draft Memorandum being proposed by FDA.

In particular, I object to the definition of "**inordinate amount**" which restricts the availability and the right to obtain **medically necessary compounded medications** by limiting the number of prescriptions that can be shipped accross states lines from specialized compounding pharmacies.

SINCERELY,

Sofie Kirschman
SOFIE KIRSCHMAN

MEDICAL CONSUMER

98N-1265

C2442

The FDA and Formulary Pharmacies: Your Right to Choose

Formulary pharmacies have been serving patients for decades. I've long worked with formulary pharmacies throughout the United States in an effort to help my patients get customized care—designed especially for them—utilizing a team approach in which the pharmacist, the physician, and the patient work together to meet the patient's unique needs. This approach has become so popular and so effective that—wouldn't you know it?—the FDA is now attempting to introduce legislation to limit the ability of formulary pharmacies to ship medications meant for personal use across state lines. The reason: Large, multimillion-dollar pharmaceutical houses want to capture this market by forcing out the individuals who have long known that “one size doesn't fit all.”

If these interests force out the formularies, then medication choices will be determined by mass-market pharmaceutical houses only, not individual doctor-patient-pharmacist teams working in a time-honored tradition that goes back for centuries.

The FDA is currently circulating a memorandum to state pharmacy boards all over the country. If this document is adopted by the state boards, you'll no longer be able to get the specialized medications you need from your formulary pharmacy because they won't be able to ship to you. Since many areas of the country do not have formulary pharmacies, many of you would not be able to get your prescriptions for natural hormones once this legislation is passed.

Here's where you come in. You can help protect your right to choose by sending your comments ASAP to:

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pounded medications by limiting the number of prescriptions that can be shipped across state lines from specialized compounding pharmacies.

Warmly,

Christiane Northrup M.D.

Christiane Northrup, M.D.
Editor

P.S. In the local paper this morning there were two news stories that caught my eye. One was about the ongoing ethnic cleansing of the Albanians by the Serbs. The other concerned a decades-long dispute between two local towns about where the ferry from one of our local islands should land. This local island conflict has always been a symbol for me of how difficult it is to live peacefully with others, leaving me to wonder how we expect the Serbs and Albanians to get along if we can't solve relatively minor problems here in Maine?

I've come to the conclusion that there's only one place where we can find peace on a consistent basis. It is within our own hearts. When we can create peace inside ourselves, it gets carried into our cells and we can heal our bodies. It can also heal our lives and begin to heal the lives of others around us. A peaceful heart is powerful medicine. In this season of renewal, may you find the courage to create health by starting with a peaceful and courageous heart.

References

Introduction

1. Coleman, Brenda C., Associated Press, "Fatty diet and breast cancer: no link?" Portland Press Herald, Wednesday, March 10, 1999.

Massage

1. Field, T. et al., 1997, "Massage therapy effects on depression and somatic symptoms in chronic fatigue syndrome," *J. of Chronic Fatigue Syndrome*, vol. 3, pages 43-51.
2. Arkko, P.J. et al., 1983, "Effects of whole body massage on serum protein, electrolyte, and hormone concentrations, enzyme activity, and hematological parameters," *International J. of Sports Medicine*, vol. 4, pages 265-267.
3. Field, T. et al., 1996, "Massage therapy reduces anxiety and enhances EEG pattern of alertness and math computations," *International J. of Neuroscience*, vol. 86, pages 197-205.
4. Field, T. et al., 1997, "Labor pain is reduced by massage therapy," *J. of Psychosomatic Ob/Gyn*, in press.

Heart

1. Childre, Doc, and Martin, Howard, *The HeartMath Solution*, HarperSanFrancisco, 1999.
2. Berger, Judith, *Herbal Rituals*, St. Martins Press, 1998.
3. Skinner, James, "Neurocardiology: brain mechanisms underlying fatal cardiac arrhythmias," *Neurologic Clinics*, vol. 11, no. 2, May 1993, pages 325-351.
4. Barbara Hand Clow, *Liquid Light of Sex: Understanding Key Life Passages*, Bear and Co., 1991.

Iron

1. Williams Obstetrics, 20th edition, Appleton and Lange, 1997.
2. Sullivan, Jeremy L., "Stored iron and ischemic heart disease: empirical support for new paradigm." *Circulation*, September 8, 1992.
3. Tzou, A. et al., "Dietary iron in coronary heart disease risk," *American J. of Epidemiology*, vol. 147, 1998, pages 161-166.
4. Corti, MC, et al., "Serum iron level, coronary artery disease, and all-cause mortality in older men and women," *American J. of Cardiology*, Jan. 15, 1977, vol. 79, no. 2, pages 120-127.

Coming Soon

An Update on Using Gems to Create Health

The Facts Behind Hypothyroidism at Mid-life

The Relationship Between How Your Skin and Bones Age

My Calendar

I am currently busy finishing my book on mothers and daughters and taping two new programs for PBS—one on menopause and one on nutrition. I will let you know of my speaking engagements in coming issues. —C.N.

Don't miss this month's
WISDOM Wire
Call 301/762-6061

Christiane Northrup, M.D., editor of *Health Wisdom for Women*, has been in private practice in southern Maine since 1979. A graduate of Dartmouth Medical School and a former president of the American Holistic Medical Association, Dr. Northrup is an assistant clinical professor at the University of Vermont School of Medicine. She is author of the acclaimed *Women's Bodies, Women's Wisdom* and is at work on a book about mothers and daughters.

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